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ACRP Certified Professional Exam Sample Questions (Q49-Q54):

NEW QUESTION # 49

Access to study documentation for auditors and inspectors during an audit or inspection at a clinical trial site is the responsibility of the:

- A. Sponsor
- B. CRC
- C. PI
- D. CRA

Answer: C

Explanation:

The Principal Investigator (PI) is responsible for providing access to study documentation during an audit or inspection. This includes regulatory files, participant records, and study logs. The PI ensures that auditors and inspectors have appropriate access while maintaining the confidentiality of subject data.

GCP guidelines clearly assign the responsibility for maintaining and granting access to trial documentation to the PI at the study site.

"The PI is responsible for ensuring that study-related documents are available for review during audits or inspections." Objectives:

- * Maintain transparency during inspections.
- * Ensure compliance with documentation requirements.

NEW QUESTION # 50

Upon receipt of temperature-controlled IP, the study staff noticed the IP incurred a temperature excursion during transport. What should the staff do NEXT?

- A. Register IP in IWRS, quarantine and notify sponsor of the excursion.
- B. Dispose of IP and request replacement from sponsor.
- C. Quarantine IP without registering in IWRS and request replacement from sponsor.
- D. Register IP in IWRS and continue with subject allocation.

Answer: A

Explanation:

If a temperature-controlled IP has experienced a temperature excursion during transport, the appropriate action is to register the IP in the Interactive Web Response System (IWRS), quarantine it to prevent use, and immediately notify the sponsor. This procedure ensures that the IP is not used until the sponsor evaluates its stability and suitability.

GCP guidelines state that any IP affected by a temperature excursion should be quarantined and reported to the sponsor for evaluation.

"Upon identification of a temperature excursion, the IP must be quarantined and reported to the sponsor to determine its usability."

Objectives:

- * Maintain IP integrity and compliance with storage conditions.
- * Follow protocol for managing temperature excursions.

NEW QUESTION # 51

A serious unexpected ADR is one:

- A. Severity and nature of the reaction is consistent with protocol.
- B. That does not need to be reported to the IRB/IEC.
- C. That results in the death of the subject.
- D. Where the severity of the reaction is not consistent with IB.

Answer: D

Explanation:

A serious unexpected adverse drug reaction (ADR) is characterized by an event that is not consistent with the information provided in the Investigator's Brochure (IB). Such reactions may indicate new risks associated with the investigational product and warrant immediate reporting to the sponsor and regulatory authorities.

This answer follows the ICH E6(R2) GCP guidelines, which specify the criteria for reporting serious and unexpected adverse events.

"An unexpected adverse drug reaction is one whose nature or severity is not consistent with the applicable product information (e.g., IB)." Objectives:

- * Understanding classification of ADRs
- * Ensuring timely and accurate reporting of unexpected events

NEW QUESTION # 52

A sponsor wants to transfer duties to a CRO. Which of the following statements is the MOST correct?

- A. The IRB/IEC must approve the transfer of duties to a CRO.
- B. Regulatory authorities must be notified promptly of the transfer of any duties to a CRO.
- C. Any trial-related duties can be documented as transferred by verbal agreement.
- D. All duties transferred to a CRO should be specified in writing.

Answer: D

Explanation:

When a sponsor transfers specific tasks to a Contract Research Organization (CRO), it must be documented in writing. This formal

documentation clearly delineates responsibilities and ensures that both parties are aware of their roles and obligations. Verbal agreements are not sufficient for regulatory compliance.

ICH E6(R2) GCP guidelines mandate that all delegated tasks must be documented formally to ensure clarity and compliance.

"The sponsor should document in writing any responsibilities transferred to a CRO to ensure clear delineation of roles." Objectives:

- * Maintain clear documentation of delegated tasks.
- * Ensure compliance with regulatory standards.

NEW QUESTION # 53

A sponsor writes a protocol comparing an IP XYZ to a marketed drug ABC to determine if XYZ is more efficacious in the target population than ABC. Both drugs are prepared in identically masked IV bags and distributed according to the randomization scheme outlined in the protocol such that the study team is unaware of the treatment assignment.

Which of the following is an appropriate title for this study?

- A. A randomized, double-blind, superiority study comparing the efficacy of XYZ to ABC in the target population
- B. A randomized, double-blind, double-dummy, superiority study comparing the efficacy of XYZ to ABC in the target population
- C. A randomized, open-label, comparator study comparing the efficacy of XYZ to ABC in the target population
- D. A randomized, single-blind, placebo-controlled study comparing the efficacy of XYZ to ABC in the target population

Answer: A

Explanation:

Since both the investigator and the participant are unaware of the treatment assignment, the study is classified as double-blind. The study aims to establish the superiority of XYZ over ABC, making it a superiority study.

The use of masked IV bags confirms the double-blind design.

The answer is verified from GCP guidelines on blinding and superiority study designs.

"In double-blind studies, neither the participant nor the investigator knows the treatment assignment, which prevents bias."

Objectives:

- * Understanding blinding methods in clinical trials
- * Ensuring unbiased efficacy comparisons

NEW QUESTION # 54

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